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(71) Applicant(s)
MSP Corporation
(Incorporated in USA - Minnesota)
Suite 206, 1313 Fifth Street S.E., Minneapolis, MN 55414, United States of America

(72) Inventor(s)
Virgil A. Marple
Daryl L Roberts
Benjamin Y H Liu

(74) Agent and/or Address for Service
Boult Wade Tennant
Verulam Gardens, 70 Gray's Inn Road, London, WC1X 8BT, United Kingdom

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G01N 15/02

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US 4274846 A

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(54) Abstract Title
Cascade impactor for classifying particles

(57) A compact cascade impactor is formed to classify particles carried in a flow through the impactor. The impactor has collection chambers 46,48 etc that are arranged to conserve space and yet provide a large flow passageway. The collection chamber may be tear drop shaped and being nested together. The impactor includes nozzles 44,56 etc that are used across a desired flow range without changing the nozzles. The impactor includes a pre-separator (16, figs. 1,8) at the inlet of the impactor housing for separating out larger particles. Two stacked or tower-like arrangements are also disclosed, one including tear drop shaped collection chambers (figures 13 and 16).

FIG. 3

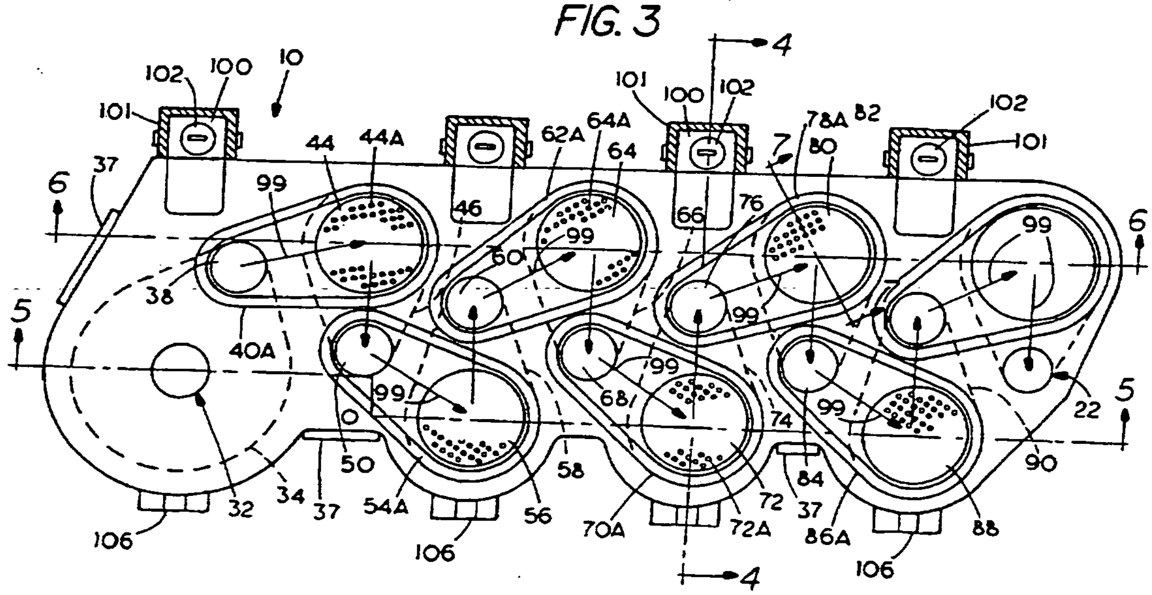

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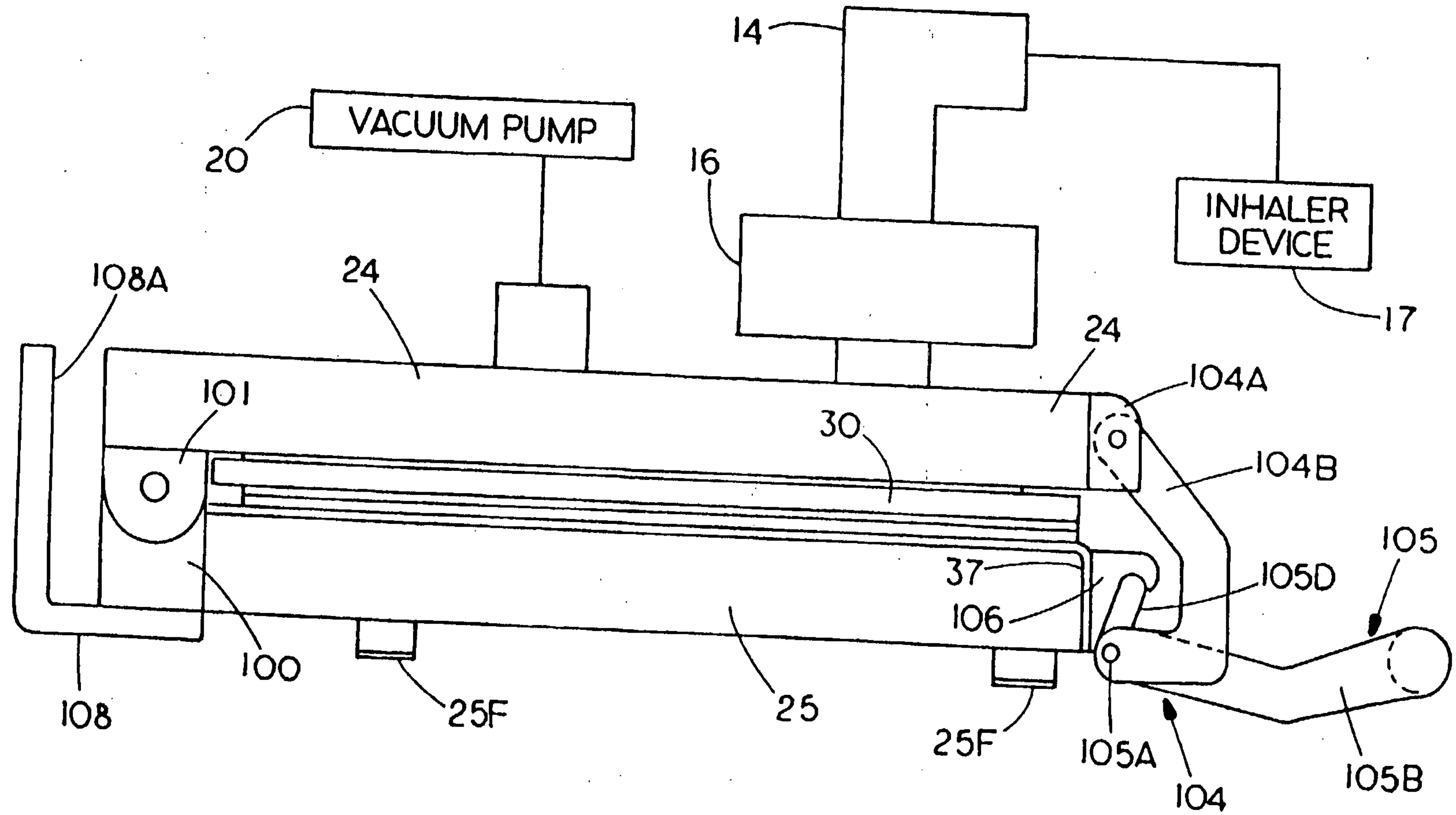
FIG. 1



VACUUM PUMP
INHALER
DEVICE
14
16
17
20
24
24
25
25F
25F
30
37
100
101
104
104A
104B
105
105A
105B
105D
106
108
108A

FIG. 2

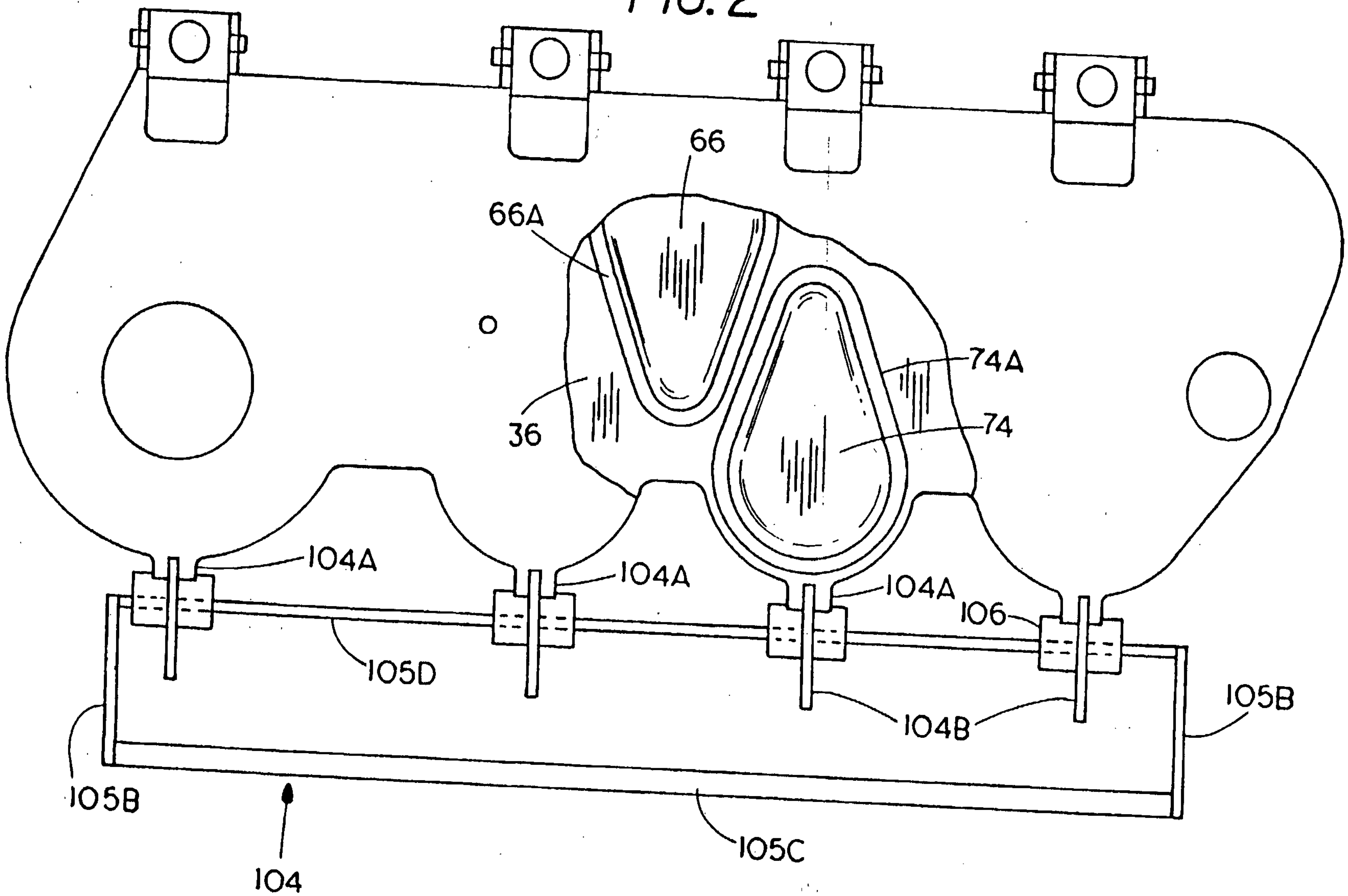
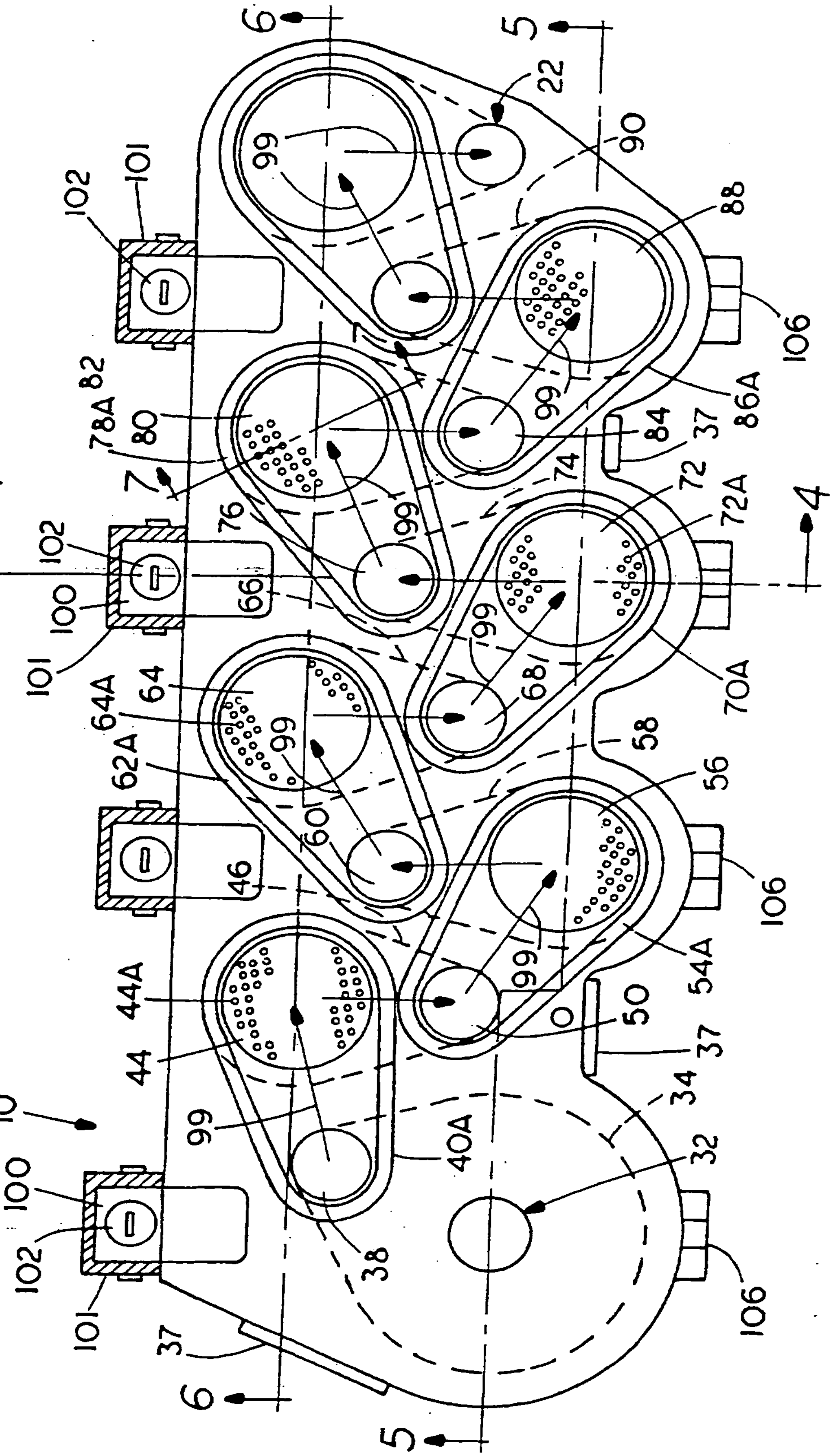

66
66A
36
74A
74
104A
104A
104A
106
105D
104B
105B
105B
105C
104

FIG. 3


10
22
32
34
37
38
40A
44
44A
46
50
54A
56
58
60
62A
64
64A
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68
70A
72
72A
74
76
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86A
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102
106
4
5
6
7

FIG. 3A

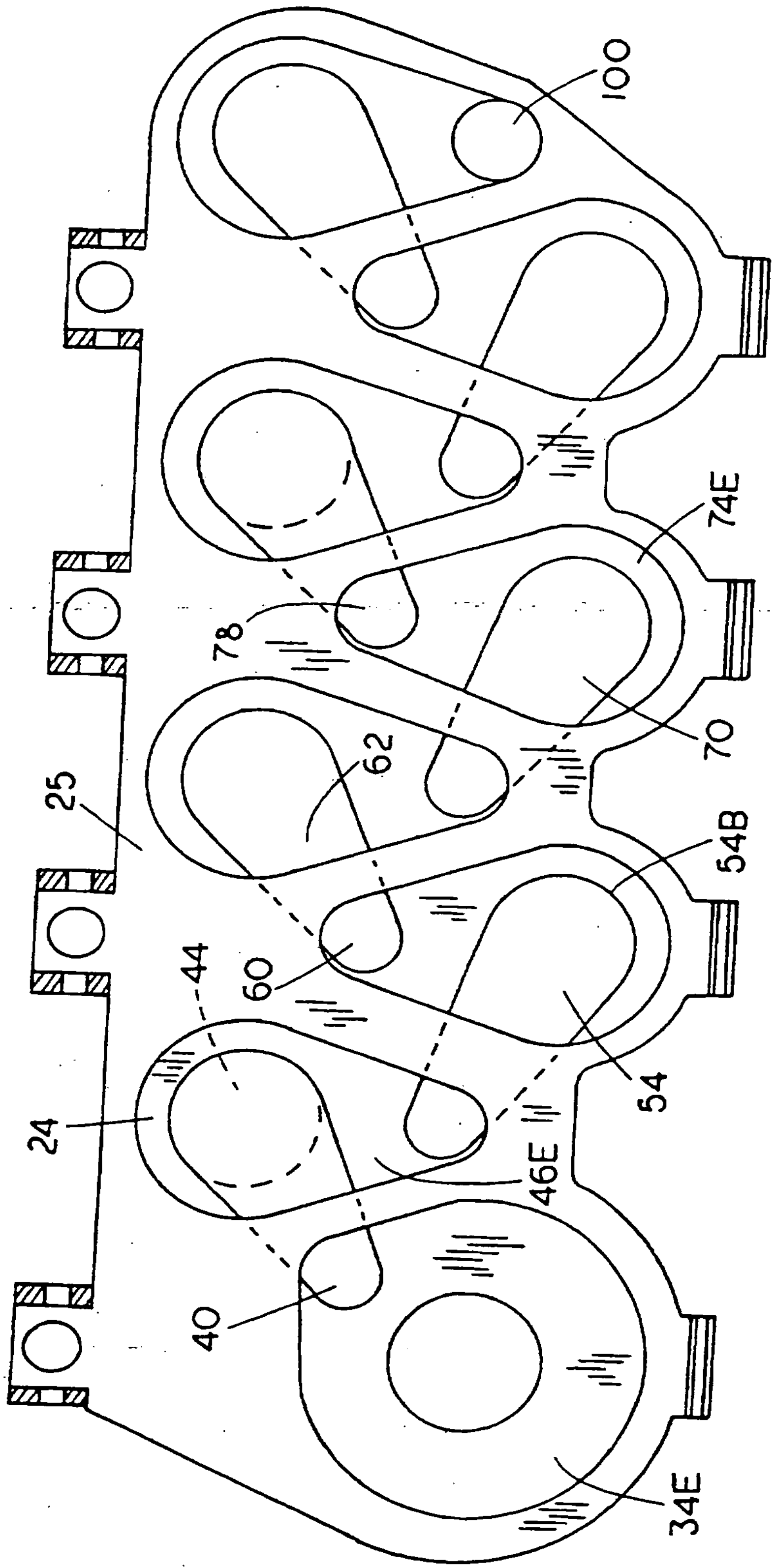

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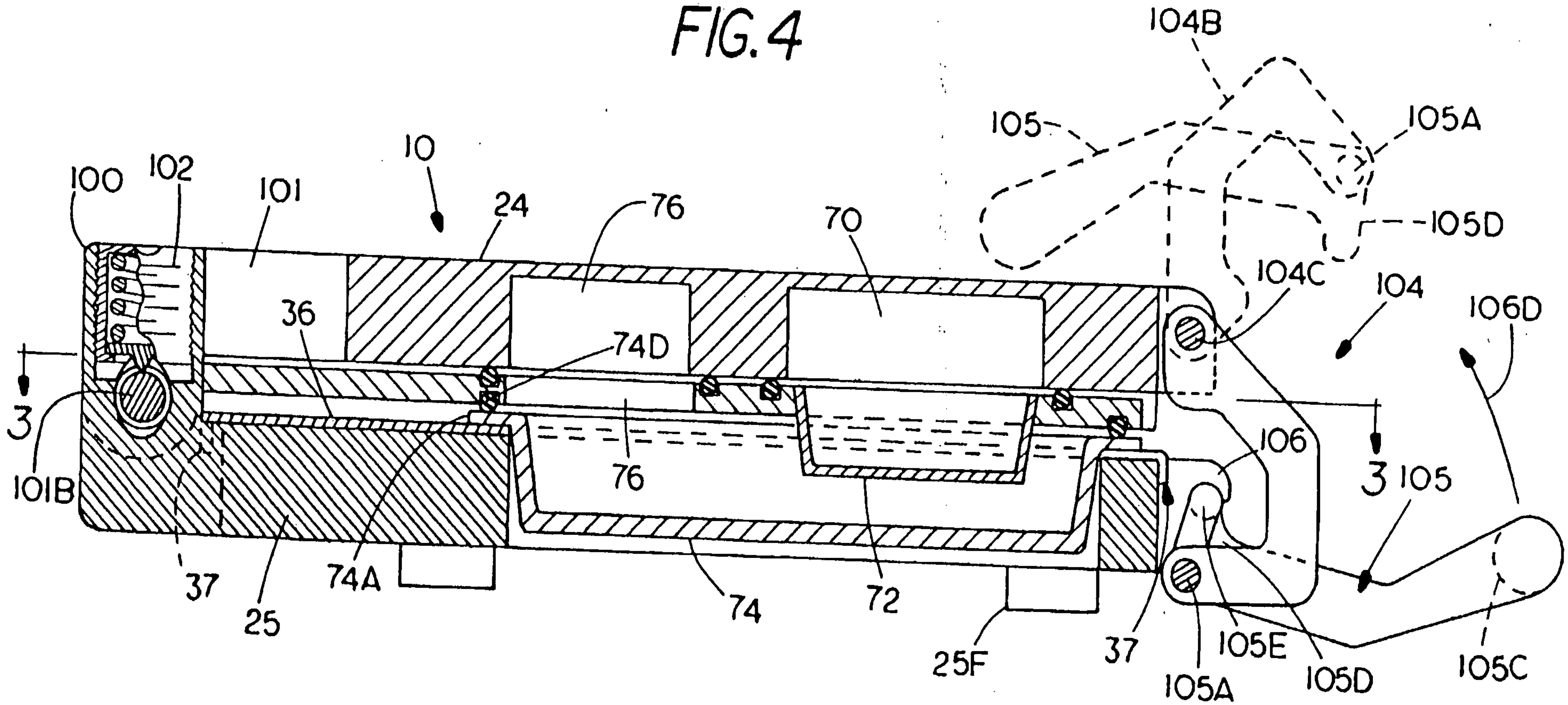
FIG. 4



100
102
101
10
24
76
70
36
74D
76
3
101B
37
25
74A
74
72
25F
37
104B
105
105A
105D
104C
104
106D
106
3
105
105E
105A
105D
105C

6/14

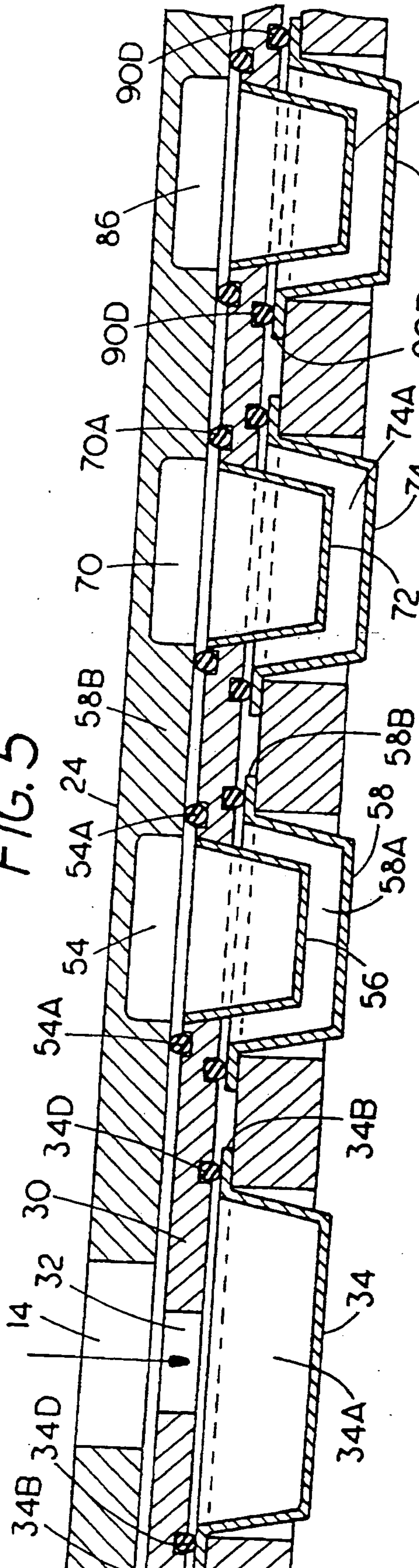


FIG. 5

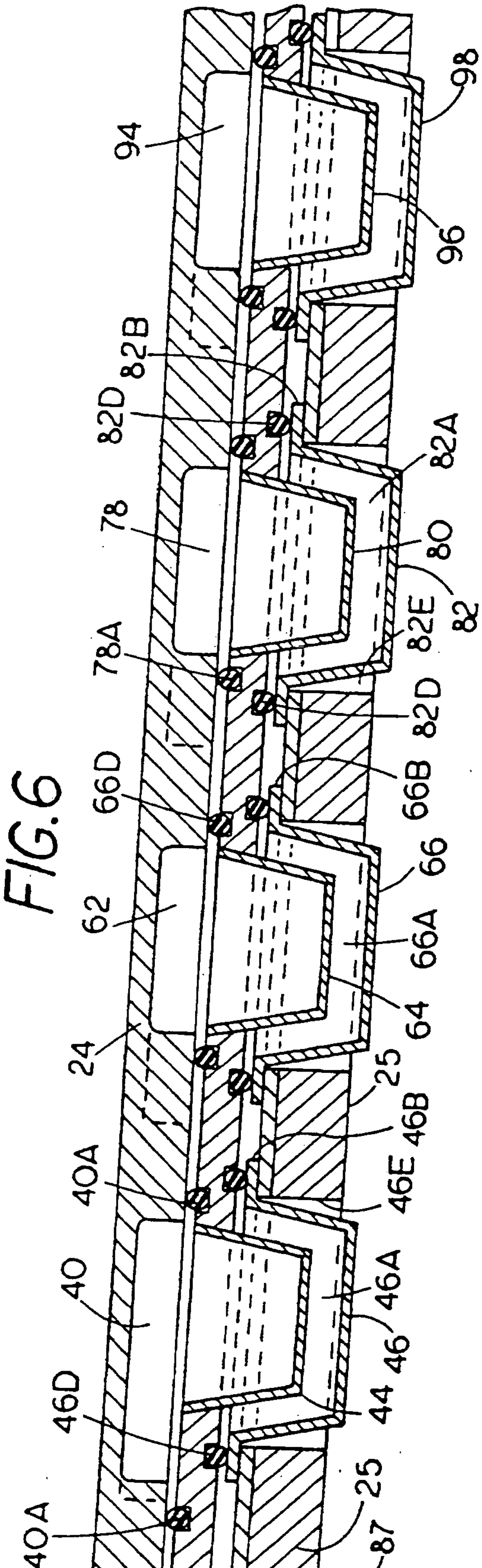


FIG. 6

FIG. 7

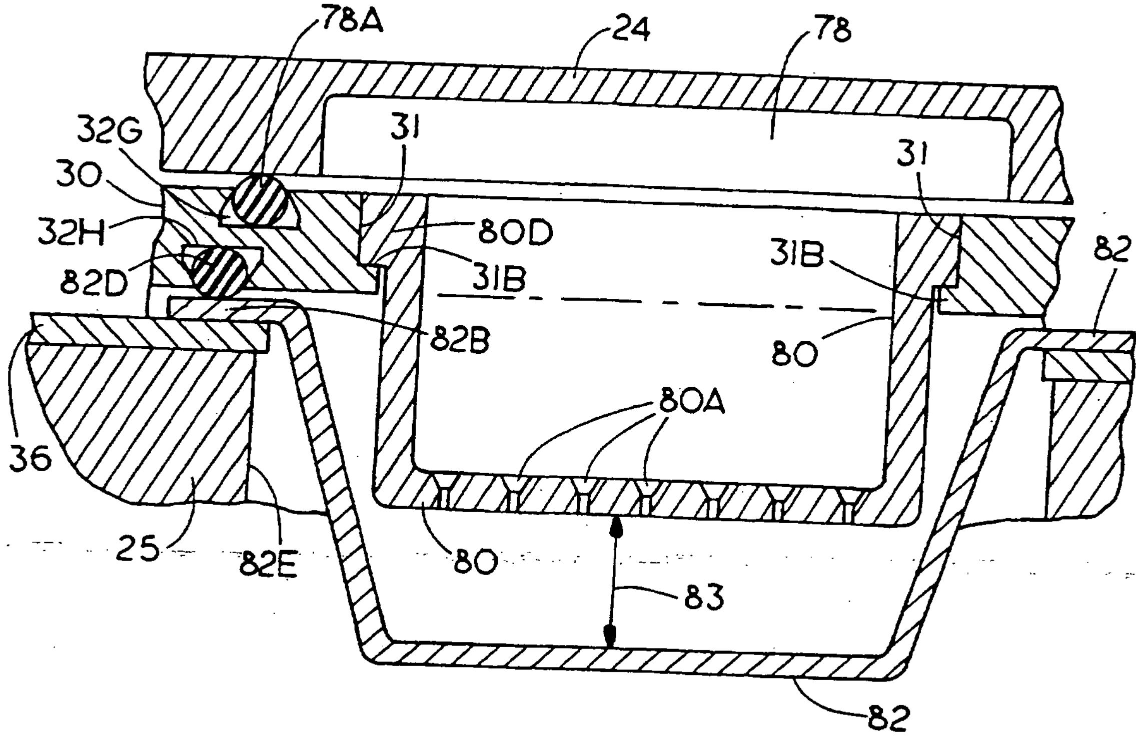

78A
24
78
32G
31
31
30
32H
80D
31B
31B
82B
82D
82B
80
36
80A
25
82E
80
83
82

FIG. 9

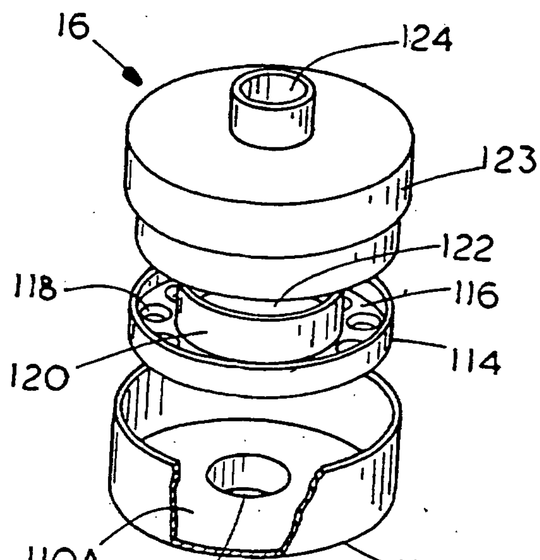

16
124
123
122
118
116
120
114
110A
112
110

FIG. 8

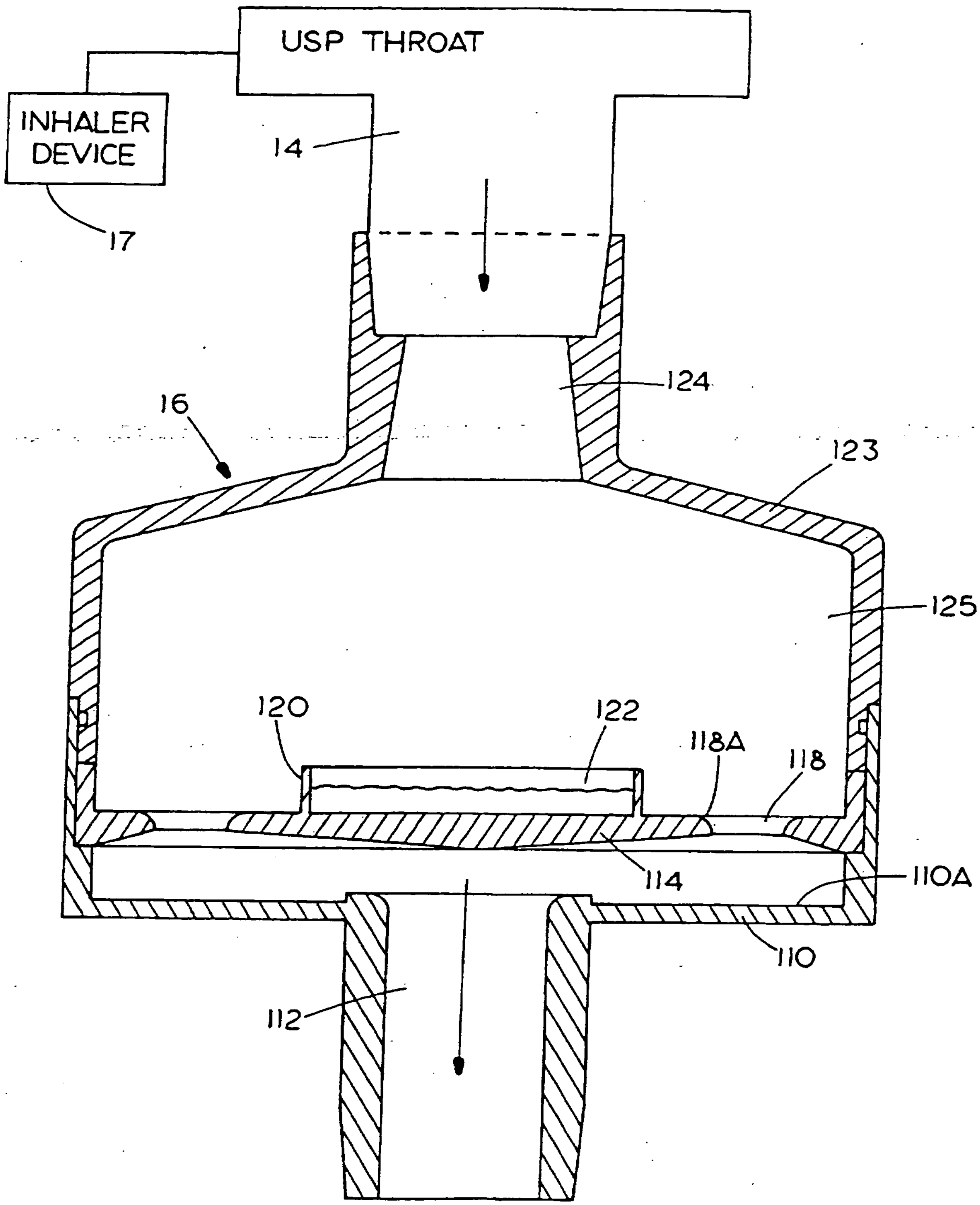

USP THROAT
INHALER DEVICE
14
17
16
124
123
125
120
122
118A
118
114
110A
110
112

FIG. 10

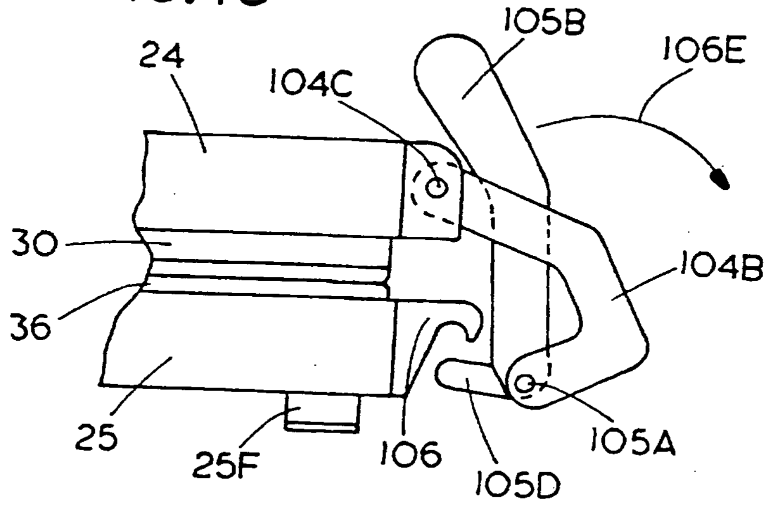


FIG. 11

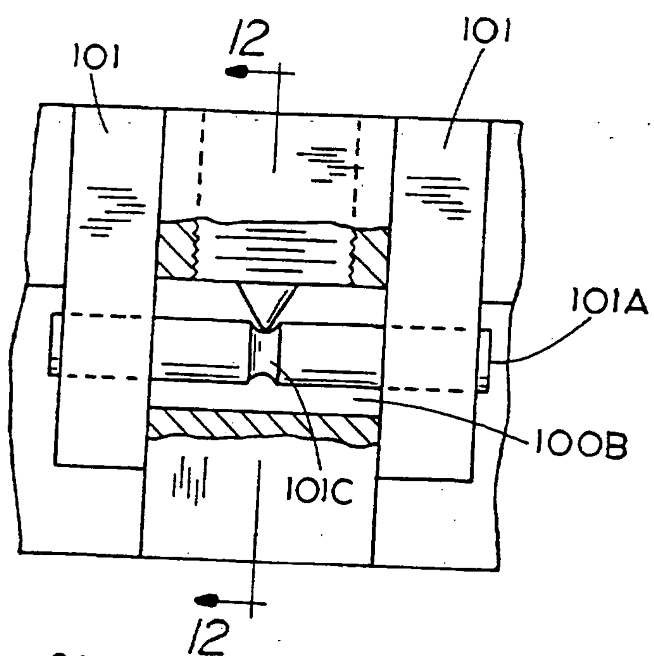


FIG. 12

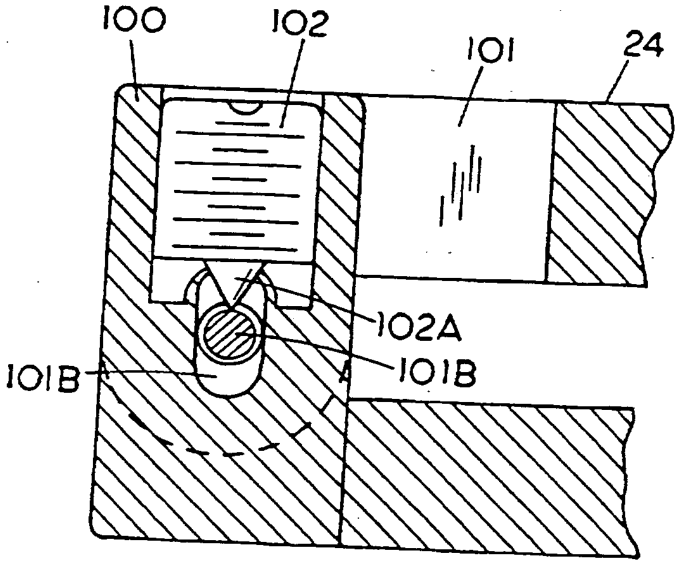
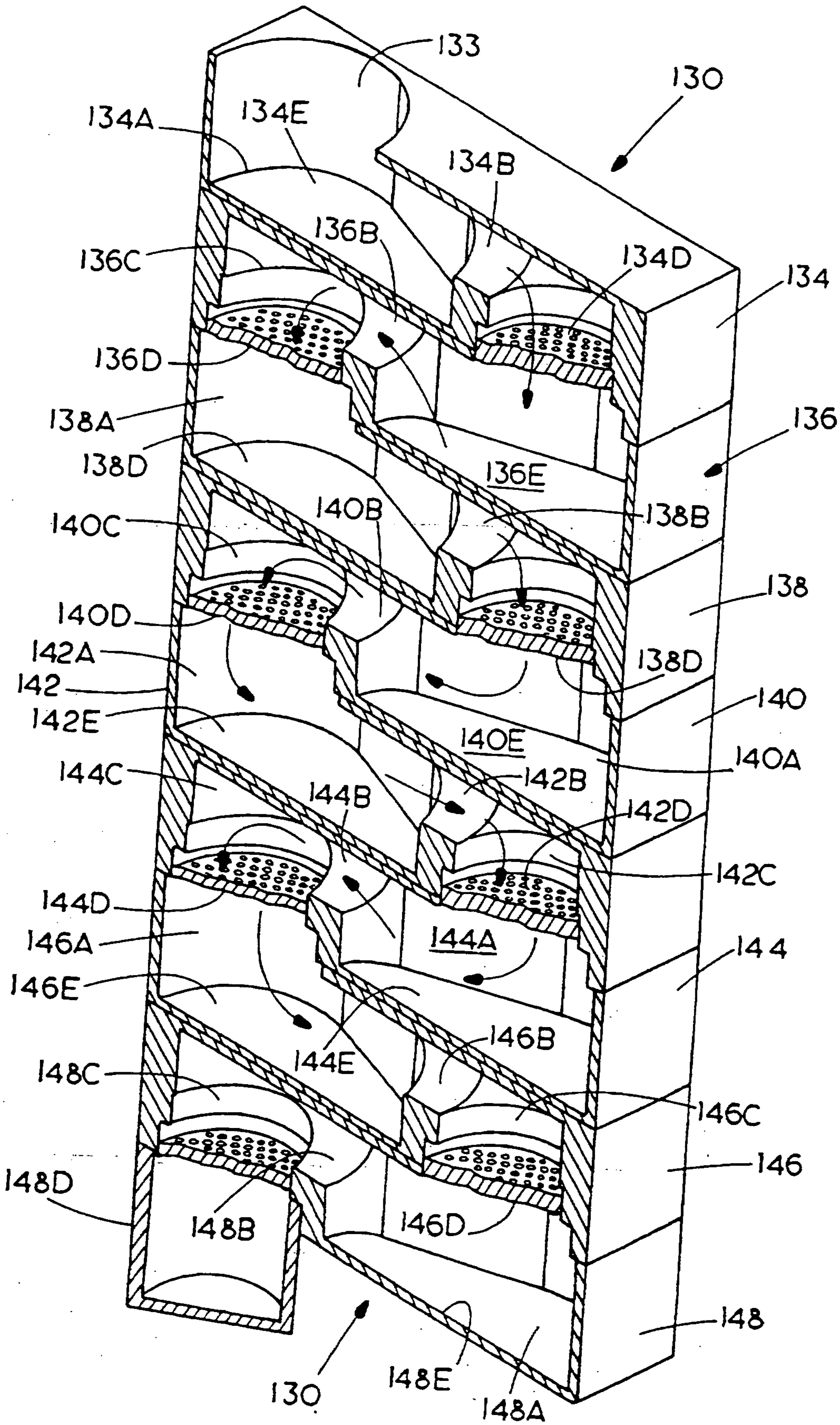


FIG. 13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134A
134E
134B
136B
136C
134D
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136D
138A
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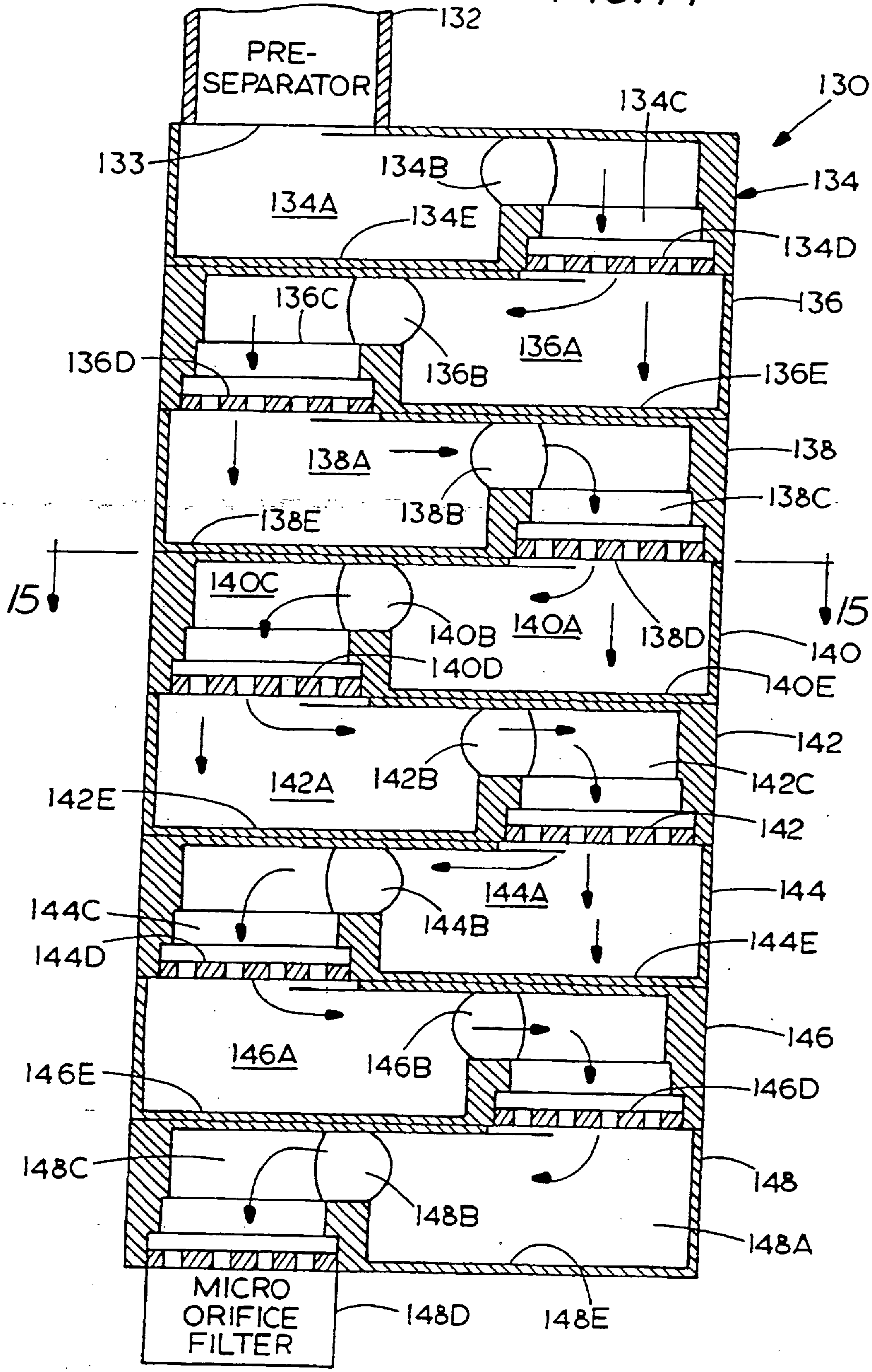
140D
138
142A
138D
142
140
142E
140E
140A
144C
142B
144B
142D
142C
144D
146A
144A
144
146E
146B
144E
148C
146C
146
148D
148B
146D
148
130
148E
148A

FIG. 14


PRE-
SEPARATOR
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134C
134B
134A
134E
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134D
136C
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136D
136A
136B
136E
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138A
138C
138E
138B
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140A
138D
140
140D
140E
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142C
142E
142A
142B
142
144
144A
144C
144B
144D
144E
146
146A
146B
146E
146D
148C
148
148B
148A
MICRO
ORIFICE
FILTER
148D
148E

FIG. 15

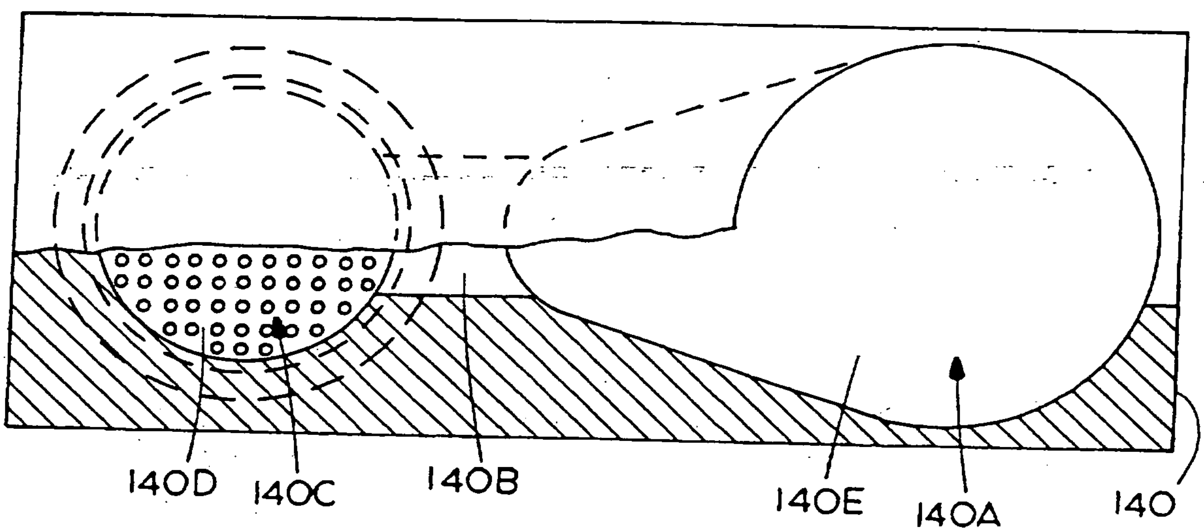
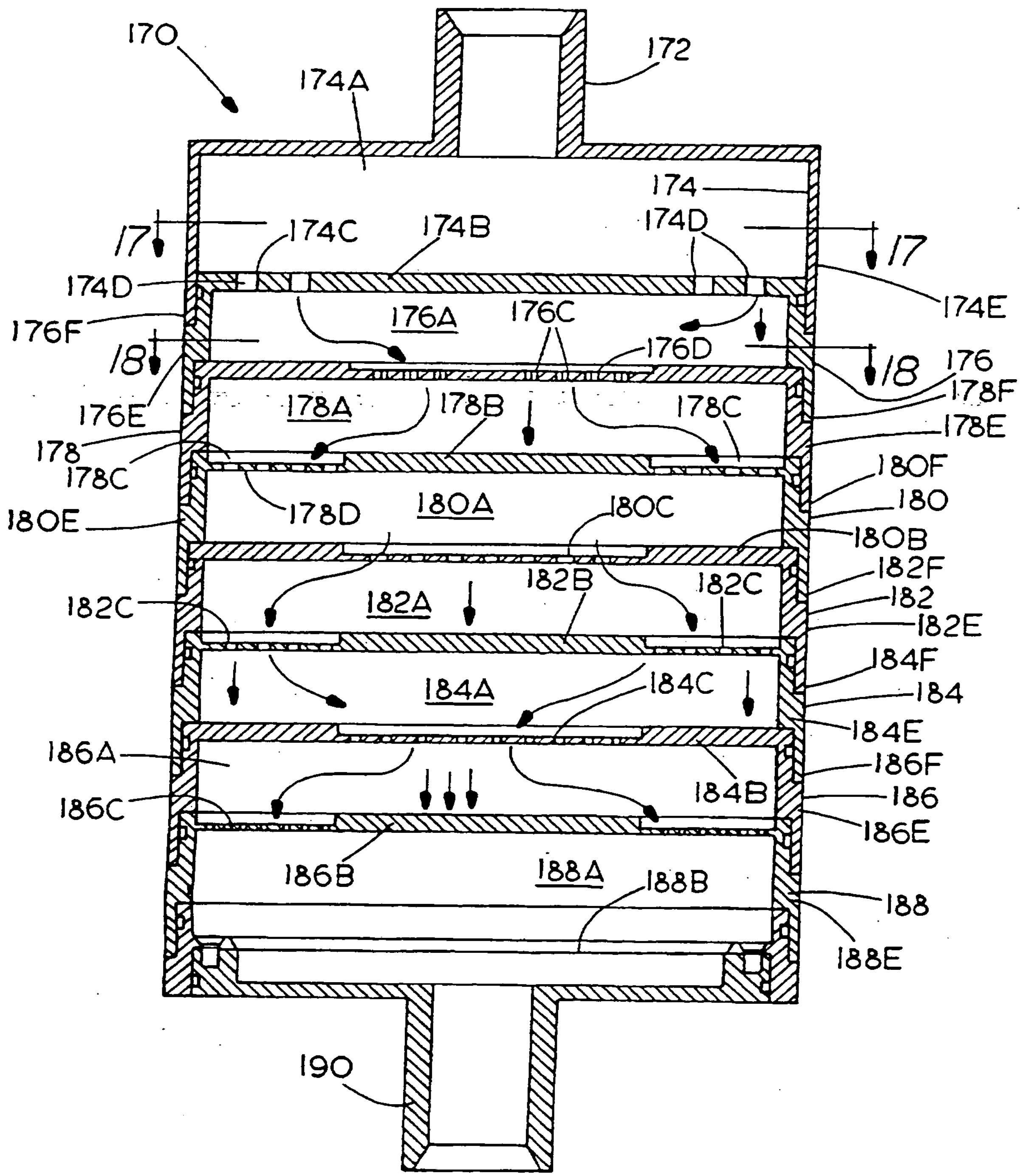


FIG. 16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178C
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178E
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180C
180F
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180E
180B
182A
182B
182C
182C
182F
182
182E
184A
184C
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186C
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186E
184B
186B
188A
188B
188
188E
190

FIG. 17

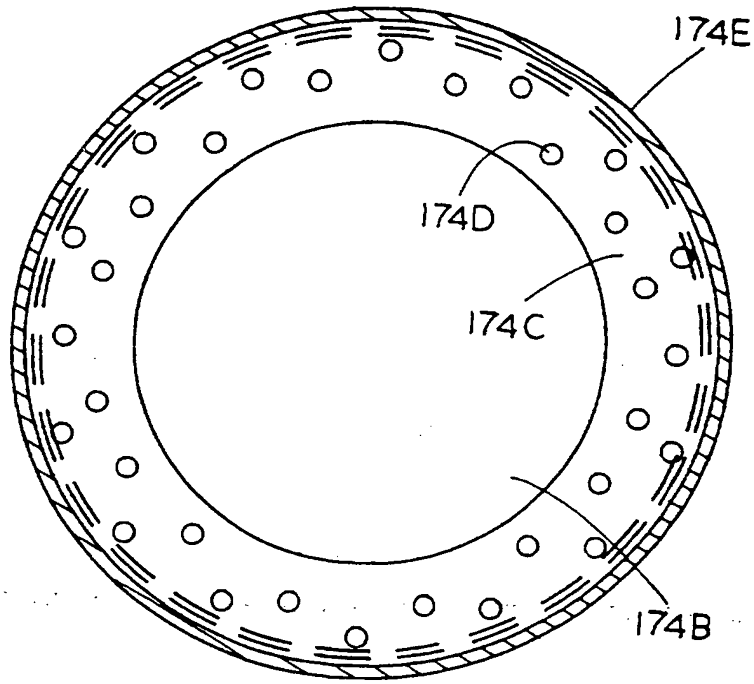
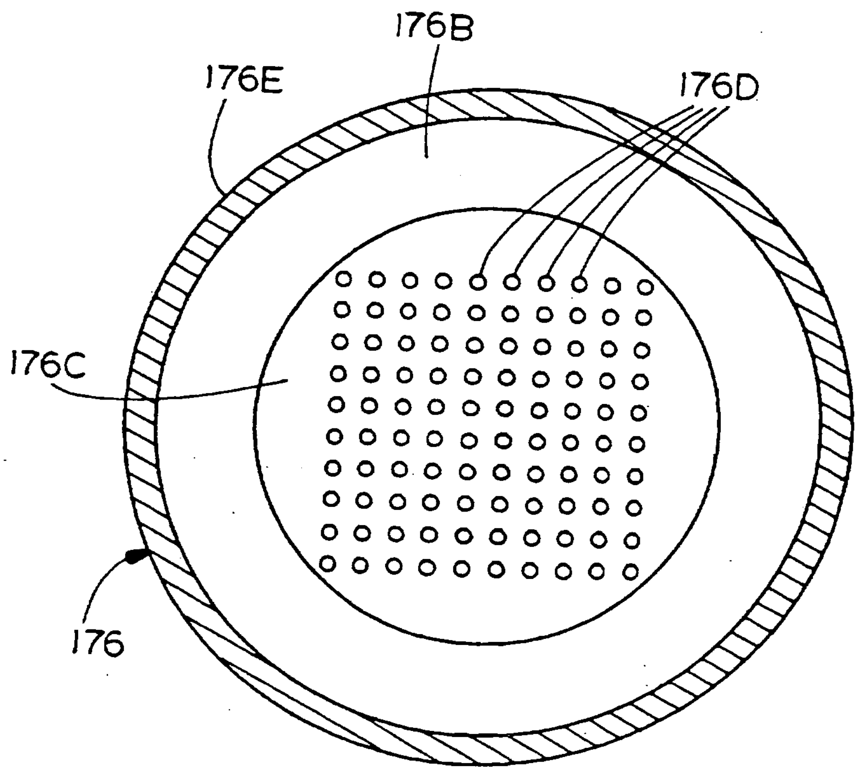


FIG. 18



EFFICIENT HIGH-PRODUCTIVITY CASCADE IMPACTORS

The present invention relates to a particle impactor used for classifying particles according to size for analysis of the particles carried in a gas flow. Sharp particle cutoff is obtained, with compactly arranged impactor/collection cups and flow channels for conserving space, and providing accurate information about the particles.

Various types of impactors have been utilized in the prior art, including devices that use cascading elements for obtaining a classification of particles. Generally a cascade impactor has a plurality of collection stages arranged in series, with each stage having a nozzle or orifice plate with nozzle openings smaller in size than those of the previous stage, and also having an impaction surface for the collection of the particles that are too large to be carried farther in the fluid stream. At the smaller nozzle openings, the velocity of the fluid carrier is higher, and the particles have a higher velocity moving through the nozzle. The higher the flow velocity through the nozzle, the smaller the particles that are collected on the impaction plate. In other words, particles larger than the cut size of an impactor will impinge upon the impaction surface and the rest of the particles will pass with the fluid or airstream to the next stage. The particles that are collected at each stage can be analyzed by weight, or by quantitative chemical analysis. When the particles are to be chemically analyzed, it is desirable to collect the particles in a container or cup so the particles easily can be transported to a lab for analysis.

Another problem that arises with impactors is loss of particles due to the collection of some particles on surfaces other than the particle impactor surface, the collection on surfaces other than the impactor surface results in losses and these are called interstage particle loss. Minimizing such interstage particle loss is a desirable feature of the present invention.

The present invention relates to a compact, high productivity cascade impactor that is easily used, manually or with a robot system and which provides for a broad flow range with quite precise particle cutoff sizes at the various stages. The physical construction makes the impactors of the present invention easily automated, and the usual final filters can be eliminated from the system and a microporous plate filter provided to avoid errors that may arise by contaminants on conventional filters.

The interstage passageways and the nozzles are designed so that they have low particle losses. The impactors thus are acceptable to regulators, such as the Food and Drug Administration and the British and European equivalents.

The impactor preferably has cups that are supported on a tray or frame. The cup tray and all the cups can be removed as a separate unit for quantitative recovery of material from the cups. The cup shape is chosen to reduce the space occupied by the impactor while not compromising the aerodynamic performance of the impactor.

A preferred form of the invention conserves space by utilizing teardrop shaped interstage passageways and collection cups. Other forms include stacked impactors, in order to provide for unique and

compact units. The impactors are preferably constructed of inert materials, and are physically robust, and since they are metal and can be grounded they are unaffected by static.

The present invention is made with one set of fixed nozzles to achieve the desired range of particle size cut points, from about 0.5 μm to 10 μm at seven different cut points. At any flow rate, five or more of these are within the range desired for assessing the safety and efficacy of the drug formulation. The impactor is designed to accept a wide range of flows, for example between 30 liters per minute and 100 liters per minute, which is the typical flow range for testing inhalables as described in the United States Pharmacopoeial (USP) or corresponding British, European or Japanese Pharmacopoeials.

In one embodiment the invention comprises an impactor for classifying particles according to size comprising a housing, a flow passageway through said housing, said flow passageway being divided into a plurality of individual passageway sections, a separate nozzle in each passageway section for carrying the flow between individual passageway sections, a particle collection chamber aligned with each nozzle and having an impaction surface to receive flow from the respective nozzle, each chamber having a output end joining other parts of said flow passage, said particle collection chamber having a large area portion immediately below its aligned nozzle, and having side walls tapering to a narrow portion at the output end of said collection chamber.

In another embodiment the invention comprises an improvement to an impactor having a housing with an inlet and an outlet, and a flow path through the

housing, which is divided into at least two flow segments, and a nozzle between the flow segments, a collection chamber for receiving flow from the nozzle for collecting particles that are carried in the flow, wherein the improvement is a pre-separator at the inlet of the housing, said pre-separator including a chamber having an inlet tube and an outlet tube, and having tapered internal surfaces that taper toward one of the tubes for permitting draining of material on the interior of the pre-separator.

The embodiments of the invention also include an impactor for classifying particles according to size comprising a housing, said housing being made up of individual housing sections, said housing sections each including a nozzle, and an impaction surface supported on substantially the same plane, and said housing sections being stacked, one on top of another.

Preferred embodiments of the invention will be described in reference to the drawings, in which:

Figure 1 is a side view of an impactor made according to the present invention;

Figure 2 is a top plan view thereof with parts broken away;

Figure 3 is a top plan view thereof with the top cover removed;

Figure 4 is a sectional view taken as on line 4--4 in Figures 2 and 3;

Figure 5 is a sectional view taken as on line 5--5 in Figures 2 and 3;

Figure 6 is a sectional view taken as on line 6--6 in Figure 2;

Figure 7 is an enlarged sectional view taken on line 7--7 in Figure 3;

Figure 8 is an exploded perspective view of a pre-separator that can be used with the present impactor;

Figure 9 is an enlarged sectional view of the pre-separator shown in Figure 8;

Figure 10 is a fragmentary side view of a latch in position about to close;

Figure 11 is an enlarged rear view of a typical cover hinge;

Figure 12 is a sectional view taken on line 12--12 in Figure 11;

Figure 13 is a perspective sectional view of a modified form of the invention;

Figure 14 is a side sectional view of the device of the impactor shown in Figure 13;

Figure 15 is a plan view of one section of the impactor in Figure 14 taken along lines 15--15 in Figure 14;

Figure 16 is a vertical sectional view of a further modified form of the present invention;

Figure 17 is a sectional view taken along line 17--17 in Figure 16; and

Figure 18 is a sectional view taken along line 18--18 in Figure 16.

A first form of the invention illustrated in Figures 1 through 9 comprises an impactor assembly 10, which has a housing assembly 12, with an aerosol inlet 14 of standard size described in USP 24, Section 601. The inlet can be a standard USP type inlet tube. A pre-separator 16 is illustrated on the inlet in Figure 1, and it is used to separate out large particles with a standard type impactor arrangement. The pre-separator is also shown in detail in Figures 8 and 9.

The aerosol that is passed through the impactor 10 is an aerosol generated by a hand-held inhaler 17 or other device that may be a liquid or dry powder drug inhaler, such as those used to control asthma and similar problems. The amount of flow from each charge is small, so the internal volume of the impactor 10 must be kept low. For testing dry powder inhalers, accepted methods call for the total volume of sampled air to be between 2 liters and 4 liters. Therefore, the internal volume of the impactor must be low to achieve proper particle sizing. The internal volume or dead volume is preferably 1 to 2.5 liters. Small dead volume is important for achieving steady state flow during a typical breath volume of 2 to 4 liters. Steady state flow is achieved in about .2 seconds. The entire test is completed in 2 to 4 seconds. The flow rate through the impactor will be generated in a selected manner, for example by providing a vacuum pump such as that shown at 20 on an exhaust or flow outlet opening 22 from the impactor housing 12.

The impactor 10 of the first form of the invention is made to be compact so that it is easily used, portable and does not take up much space, and can be operated in a normal manner. The impactor 10 of the first form of the invention has a lid or cover 24 that is sufficiently thick to include flow passageways on the underside. The lid or cover 24 has the inlet 14 at one end thereof. The lid or cover 24 is hinged along one edge to a base frame 25 that has a number of egg shaped or teardrop shaped openings that receive and support impactor particle collection chambers or cups as will be shown.

As shown in Figures 3, 4, 5 and 6 a seal plate 30 is positioned just below the cover of lid 24 and as

will be explained, has seals on both sides to seal passageways on the underside of the cover and, on the opposite or bottom side of the seal plate, to seal around lips of each of the impaction chambers or cups to define sealed passageways for forming the flow path. The collection chambers or cups will be individually numbered in this description, but the first cup at the inlet is shown at 34, and is larger than the rest. Inlet opening 14 in cover 25 opens through an inlet opening 34 that sealingly opens through the seal plate 30 and cover or lid 24 into a chamber or passageway 34A defined by a first impaction stage cup 34. Cup 34 fits through an opening in a cup retainer tray or frame 36. The tray or frame 36 is supported on the top of the base 25. The cup 34 has a peripheral flange 34B that rests on the tray or frame 36. The cup also fits in an opening 34E in the frame 25.

The impaction cups are tear drop shaped as shown. The large end 34E of the first stage cup forms the impactor surface and underlies the inlet opening 32. The flange 34B of the cup 34 is sealed with a seal 34D on the seal plate and extends transversely of the impactor to a vertical passageway 38 that opens through the seal plate 30 to interface or crossover passage 40 formed on the underside of the cover 24.

Figure 3A is a bottom view of the base, with the cups and seal plate removed, so the interstage passages on the underside of the cover 24 can be seen. The openings in the cups on the base frame 25 are designated with the cup member followed by the letter "E". The seals on the periphery of the cups follow the shape of the cup openings in frame 25 shown in Figure 3A, and as shown in dotted lines in Figure 3.

The crossover or interstage passageway 40 leads to a nozzle passageway or opening in seal plate 30 (figures 3 and 6) having a nozzle 44 that has openings 44A of desired size, and desired number as will be shown in Table I, so that particles passing through the nozzle 44 will be accelerated and will discharge into a second stage impactor surface of a cup 46 that underlies the nozzle 44. The interstage passageway 40 in the cover 24 is sealed with a seal 40A (Figure 3). The nozzle thus is downwardly directed toward an underlying impaction surface. The tear drop shaped cup 46 has a wide end under the nozzle and a narrow opposite end. The cup 46 forms an impactor chamber that defines a passageway 46A that extends laterally across the seal plate 30. The flange 45B of the cup 46 is sealed with seal 46D, that encircles the cup. The cup is positioned in opening 46E of the base 25. The small end of the cup 46 aligns with a vertical passageway or port 50 that extends through the seal plate and opens into a crossover or interstage passage 54 in the cover 24. The opening 46E in the base shown in Figure 3 shows the shape of the cup 46 and passageway 46A.

The crossover or interstage passageway 54 is also tear drop shaped as can be seen in Figures 3 and 3A, and the large end 54B of passageway 54 overlies an opening in seal plate 30 which holds a nozzle 56 that has openings 56A therein. The interstage passageway 54 is sealed with a seal 54A. The openings 56A are smaller and greater in number than the opening 44A in nozzle 44. The nozzle 56 overlies a third stage impactor surface of a cup 58. The third stage impactor cup 58 is also tear drop shaped and forms a passageway 58A (see Figures 3, 3A and 5) that extends laterally back in direction toward the hinge side of the body and opens to a

vertical passageway 60 through the seal plate 30 that connects to a crossover or interstage passageway 62 in the cover 24. The seal plate has a seal 58D that seals on flange 58B of cup 58.

The crossover passage 62 also is tear drop shaped, and the large end of the crossover passage 62 opens downwardly through an opening in seal plate 30 which holds a nozzle 64 which has a selected number of openings 64A. The interstage or crossover passageway 62 is sealed with a seal 62A.

Nozzle 64 opens to a underlying cup 66 that again is tear drop shaped and provides a fourth stage impactor surface at its larger end. The cup 64 forms a passageway 64A that extends laterally back across the base or body 25 to a vertical port or passageway 68 through seal plate 30 that connects to a crossover or interstage passageway 70 in the cover 24. Passageway 70 has a larger end that opens through an opening in the seal plate 30 supporting a nozzle 72. The interstage passageway 70 is sealed with a bounding seal 70A.

A cup 74 providing a fifth stage impactor and has an impactor surface at its large end that underlies the nozzle 72 and forms a passageway 74A that extends laterally back across the base or body 25 to a vertical port or opening 76 through the seal plate 30. The cup 74 has a peripheral flange 74B that is sealed with a peripheral seal 74D. The opening 76 connects to a crossover or interstage passageway 78 in the underside of cover 24. The opening 74E in the base shown in Figure 3A is for cup 74 and shows the shape of the cups 74, looking from the bottom up. Cups 66 and 74 are also shown in Figure 1, where the cover and seal plate are broken away.

The crossover passageway 78 is tear drop shaped and opens to a nozzle supporting opening in the seal plate 30 having a nozzle 80 therein, with openings 80A that provides for a flow downwardly into an underlying sixth stage impactor cup 82. The interstage passageway 78 is sealed with a seal 78A on seal plate 30. The cup 82 forms an impaction chamber and passageway 82A. The cup 84 is tear drop shaped and has an impaction surface at its large end. The cup 82 has a flange 82B supported on the cup tray, and a peripheral seal 82D on the seal plate seals around the cup. The cup 82 extends over to an opening or passageway 84 that leads through the seal plate 30 to a crossover interstage passageway 86 in the underside of cover 24 that forms a passageway section for carrying flow.

The crossover or interstage passageway 86 is sealed with a seal 86A on seal plate 30. The passageway 86 leads to an opening in seal plate 30 that has a further nozzle 88 that has openings 88A that open to an underlying cup 90 forming a seventh impaction stage. The cup 90 is tear drop shaped and forms a passageway 90A that extends laterally to a vertical opening 92 through seal plate 30 that leads to crossover or interstage passageway 94 in the cover 24. The cup 90 has a flange 90B that is sealed with a seal 90D on the seal plate. The flange 90B is shaped like opening 90E, and rests on the cup tray 36, as to all of the cups.

The passageway 94 opens to a final stage micro orifice filter nozzle 96 supported in an opening in the seal plate 30. The passageway 94 is sealed with a seal 94A on the seal plate that has openings 96A and which discharges the fluid into an underlying cup 98 that is tear drop shaped and opens to the fluid flow outlet passage 22 from the impactor.

In Figure 7 a detailed enlarged showing of a typical way of mounting a nozzle in the seal plate is illustrated. In this instance, the nozzle 80 is illustrated, and Figure 7 is taken along line 7--7 in Figure 3.

The seal plate 30, as shown, and as was explained has "O" ring type seals thereon. The seal 78A is illustrated on the top side of the seal plate, against the surface of the cover 24, and a seal 82D is shown against the flange 82B of the cup 82. The seal receiving grooves that are formed in the seal plate 30 are shown at 30G and 30H, respectively, and are shaped so that they will permit the seals 78A and 82D, which are suitable durometer rubber, to spread slightly as the cover 24 is loaded against the seals and then the seal plate is loaded against the flange 82B, which in turn is supported by the cup tray 36. The cup tray 36 is supported on the base 25.

Each of the nozzle holders is formed with a sealing rim typically shown at 30D in Figure 7 and is positively seated in an opening 31 in the seal plate 30 against a shoulder 31B, so that the distances from the nozzle to the cup such as that shown at 83 are precisely maintained. The nozzles are made so the rim and side walls are machined from a single block of material. The actual nozzle plate having the nozzle opening will be machined on the nozzles with larger openings. When small openings are needed, the nozzles are two pieces assembled together. The bottom wall or plate can be made by other processes to get the small holes needed. Then it can be brazed or otherwise sealingly secured to the lower end of the nozzle holder.

Also, the nozzle sealing along the surface 31 insures that there will be no flow leakage, and with the

seals carried by the seal plate, which will expand into the grooves when compressed, positively sealing of each of the passageways, and on the cups along the cup flanges is maintained.

The cover 24 is hinged to the base with a hinge. As shown, a pin that is spring loaded is provided to permit some desired resilient movement perpendicular to the seal plate to provide compression of the seals on the seal plate 30. As shown in Figures 2, 4, 10, 11 and 12, the hinging between the cover 24 and the base 25 may be made so that as compression of the seals on the seal plate 30 occurs, the surfaces that engage the seal plate, namely the lips on the cups and the under surface of the cover, remain parallel.

As shown, the base 25 has a plurality of upright hinge posts 100, that are spaced along the hinging edge of the base and cover, and the cover has sets of flanges 101, that fit on the opposite sides of the posts 100. The flanges 101 carry a pivot pin 101A that passes through a slot 100B in each of the upright posts 100. The pivot pin 101B can move up and down in the slot 100B, shown in Figures 11 and 12, and the pin is urged downwardly with a spring loaded, threaded plunger 102 that is threaded into a bore in the respective hinge posts. The spring loaded plunger is a purchased unit that has an internal spring and a centering point 102A at the lower end thereof that rides in a groove 101C in the pin 101A. This will keep the pin centered and held in the hinge post 100. It can be seen then that if the pin 101B is moved so that the ears 101 on the cover tend to move upwardly, the pin 101B will have to compress the spring. When the cover is lifted, however, then the spring will be made so that it

will urge the pin downwardly toward the lower end of the slot 100B.

When the cover is closed, and the seals on the seal plate engage the respective surfaces, the design is made so that there will be a load on the spring loaded plunger 102 tending to resist movement of the cover away from the base.

In order to have an adequate compression load on the seals, a cam type latch assembly 104 is utilized, and is shown in Figures 2, 4 and 10 primarily. The latch assembly 104 is supported on ears 104A that are on the cover member, through first pivot arms 104B. The hinge members or ears 104A have pins 104C that permit the arms 104B to pivot upwardly and downwardly as shown in dotted lines in Figure 4, where the solid line position shows the cam latch assembly 104 in locked position, and the dotted line position shows it released.

The arms 104B in turn are pivoted to a latch handle assembly 105, at each of the arms, with a pin 105A positioned so that it will permit pivotal movement of the handle 105. The handle assembly 105 comprises a pair of end arm members 105B, 105B as shown in Figure 2 that are to the outside of the outer ones of the hinges 104A and first pivot arms 104B. The handle arms 105B are connected with a handle rail 105C that comprises a hand grip, and the handle arms 105B are also joined with a latch bar 105D that is carried so that it will pivot with the arms 105 as they pivot on the pins 105A. There are four of the pins 105A, one at each of the first pivot arms 104B, and the latch bar 105D, extends along the impactor front edge. As shown in Figures 4 and 10, the latch bar has a rounded nose portion 105E.

The base 25 carries a plurality of latch hooks 106, which as shown in Figures 5 and 10 have recesses facing downwardly, and the recesses in the hooks 106 are spaced from a line that passes through the axis of pin 105A and the axis of pin 104C when the latch bar is in its latched position in the hooks 106, as shown in Figure 4. This forms an over center latch, and it can be seen that the hooks 106 have a surface receive the nose portion 105E and extend parallel to the latch bar 105B.

As shown in Figure 4, when the latch is in position, the load line of the nose portion 105E is over center so that the unit is held tightly closed, and will not be released accidentally. The amount of compression of the seals can be regulated by the distance between the pivot of the pins 105A and the center of the nose 105E on the latch bar.

The handle 105C can be moved for release in direction as indicated by the arrow 106D. There is a double pivot about the pins 105A and the pins 104C so that the latch handle can be moved all the way up to a released position as shown in dotted lines in Figure 4. When the latch is to be closed, it is moved down to a position shown in Figure 10, where the pivot arms 104B are pivoted downwardly about the pin 104C, but the handle arms 105D are still "cocked" in a ready position so that the latch bar 105D is beneath the hooks 106, but not engaging them. Then, by moving the handle in direction as indicated by the arrow 106E in Figure 10, it can be seen that the latch bar 105D will tilt upwardly, and come under the hook members 106 into the seat that the nose 105E rests in, and as it does so, it will tend to clamp the cover and the base together. It

will then go over center as shown in Figure 4 in order to latch in place.

As can be seen, there are four of the hooks 106 and four of the hinges 104A. The latch provides a positive lock. The cover hinge can be a pin hinge that does not move vertically and comprises hinge pins on the cover and bores for the hinge pins on the base. The pins on the cover can be fixed to ears and slip into the bores for pivoting when the cover moves laterally so that upon reverse direction movement the pins can be removed from the base for washing. Also, instead of the latch hooks being on the base, the hooks can be on the cover, and the pivoting arms and latch bar mounted on the base.

As shown in Figure 1, the base 25 has support feet 25E, and at the hinge end, a bracket 108 is provided that can be fixed to the hinge bosses 100, and the bracket 108 has an upright leg 108A that is rigidly attached to the lower portion of the leg, and when the unit is turned up on edge, the bracket 108A will support the impactor assembly 10 with the hinge edge downwardly, and letting it stand in an upright position with the handle extended upwardly.

As can be seen in Figure 6 and other figures, the bottom surface of the base 25 is supported off the supporting surface with the feet legs 25F. The bottoms of the cups clear the supporting surface. This means that when the cover is opened, after the test has been run, tray 36 can be lifted out of the bottom frame, manually or with a fixture. When the tray is lifted all of the cups can be removed as a unit. The cups may be placed either in a separate container and sealed, or moved to another location for direct analysis.

The ability to lift all of the cups at once makes automation easier, because they can be installed in racks and moved as a unit. The cup tray has locating flanges 37 that act as feet when the tray is removed. The locator flanges 37 lap over the edges of the base to keep the tray 36 in place.

The cups also have outwardly tapered side walls so they can be nested and stacked for storage.

The flow paths are shown essentially in Figure 3, with arrows 99. The flow path is from the inlet to the outlet. The path is divided into segments, forming impaction stages, by the nozzles.

The nozzles and the orifice sizes are selected to provide at least 5 cut points at all desired flow ranges that are between 0.4 μm and 6.0 μm. In addition, one stage should provide particles between 5 μm and 10 μm. A pressure drop across the impactor of less than 100 inches of water at the maximum flow rate is desired.

The designs for meeting Pharmacopoeial standards of the present invention have fixed nozzles and flow rates between 30 liters per minute and 100 liters per minute. The cut point of particles at the first stage (at the inlet) with a flow rate of 100 liters per minute (a maximum) will provide particles of about 6.0 μm. The cut point of the last stage at a minimum design flow rate of 30 liters per minute would be 0.50 microns.

The nozzles need to be spaced appropriately, and if they are too close to each other or to the wall of the impactor body, they will tend not to collect particles well. The cluster diameter of the nozzle openings and each of the nozzles is no more than two inches at any stage, which influences the overall design.

The flow range of 30 liters per minute (minimum) to 100 liters per minute is a selected range that is in keeping with hand-held inhalers and other equipment with which this device is to be used.

The impactors of the present invention obtain the desired range of cut points without having interchangeable nozzle plates. While the cut points will shift with flow rates, with 7 stages as shown, followed by a micro orifice filter, the desired range of cut points can be obtained from 5 or more of the nozzle plates.

The micro orifice filter is a nozzle that has a large number of small holes, and takes the place of a conventional or absolute final filter typically used in impactor designs. The reason for designing the impactor with a micro orifice filter is that it is much easier to recover drug material from a micro orifice filter than from a conventional glass fiber or metallic final filter in manual and automated operations. The micro orifice filter is like an impactor stage with thousands of nozzles, each less than about a hundred microns in diameter.

The micro orifice filter is made to efficiently capture particles of about 0.1 μm to 0.2 μm, depending on the flow rate. The smallest particles captured by the micro orifice filter will be approximately 1/3 the size of the smallest particles impacted in the seventh stage of the impactor. Table I that follows shows impactor cut point characteristics obtained with the listed nozzle openings size, for three selected inlet flows in liters per minute. Table I, the "Stage Number" is the orifice plate shown in Figure 2, for example, at each of the respective numbers.

The micro orifice filter is mounted the same as the nozzles on the seal plate 30 and can be removed for cleaning, as can the nozzles. Any particles in cup 98 will also be used in analysis.

The tables that follow are for illustrative purposes.

TABLE I

Impactor Cut-Point Characteristics

Inlet Flow (LPM)	Stage Number	Nozzle Diameter (mm)	Number of Nozzles	Cut Point (μm)
100	1-32	5.49	12	6.00
	2-44	3.06	24	3.49
	3-56	1.96	32	2.03
	4-64	1.18	52	1.18
	5-72	0.597	152	0.689
	6-80	0.317	400	0.401
	7-80	0.205	648	0.233
	Micro-Orifice Filter		3100	

Inlet Flow (LPM)	Stage Number	Nozzle Diameter (mm)	Number of Nozzles	Cut Point (μm)
60	1-32	5.49	12	7.77
	2-44	3.06	24	4.53
	3-56	1.96	32	2.65
	4-64	1.18	52	1.55
	5-72	0.597	152	0.916
	6-80	0.317	400	0.546
	7-88	0.205	648	0.333
	Micro-Orifice Filter		3100	

Table I - continued

Inlet Flow (LPM)	Stage Number	Nozzle Diameter (mm)	Number of Nozzles	Cut Point (μm)
30	1-32	5.49	12	11.0
	2-44	3.06	24	6.45
	3-56	1.96	32	3.78
	4-64	1.18	52	2.23
	5-72	0.597	152	1.33
	6-80	0.317	400	0.808
	7-88	0.205	648	0.506
	Micro-Orifice Filter		3100	

Table II shows the Reynolds numbers and cumulative pressure drop for the respective nozzles at different diameters at the different stages shown in Table I.

TABLE II

Impactor Cut-Point Characteristics

Inlet Flow (LPM)	Stage Number	Nozzle Re	Cumulative Δ (inches of water)
100	1-32	2070	0.11
	2-44	1860	0.41
	3-56	2180	1.41
	4-64	2220	4.24
	5-72	1510	9.43
	6-80	1080	18.9
	7-88	1030	40.3
	Micro-Orifice Filter		88.8

Inlet Flow (LPM)	Stage Number	Nozzle Re	Cumulative Δ (inches of water)
60	1-32	1240	0.04
	2-44	1120	0.15
	3-56	1310	0.51
	4-64	1330	1.52
	5-72	905	3.38
	6-80	647	6.75
	7-88	618	14.2
	Micro-Orifice Filter		30.5

Table II - Continued

Inlet Flow (LPM)	Stage Number	Nozzle Re	Cumulative Δ (inches of water)
30	1-32	622	0.01
	2-44	559	0.04
	3-56	654	0.13
	4-64	666	0.38
	5-72	453	0.84
	6-80	323	1.68
	7-88	309	3.52
	Micro-Orifice Filter		7.47

It can be seen that the particle size cut points for each of the different stages, when having 7 stages, provides 5 stages which are within the range of .5 μm to 5.0 μm and one stage between 5.0 μm and 10.0 μm, with some variations in the ranges when single size, nozzles are used across the full range. The nozzles do not have to be changed to obtain the beneficial results.

With the inlet flow of 30 liters per minute, the cut points are essentially within the ranges desired are shown in stages 3-7, that is impactors 56, 64, 72, 80 and 88. When the inlet flow is in the nominal range of 60 liters per minute, where actual flow range may be between 50 liters per minute and 70 liters per minute, where many DPI devices will be tested, there are 5 stage cuts between 0.5 μm and 5.0 μm and one stage between 5.0 μm and 10.0 μm (stages 1-6, namely nozzles 32, 44, 56, 64 and 72). At the high flow of 100 liters per minute, stages 1-6 provide cut points between 0.4 μm and 6.0 μm. While the desired cut point is .5 μm, it is important to have one cut below .5 μm at the lowest stage, because of the fine particles that some drug companies are developing. 6 microns in stage 1 at 100 liters per minute as shown in Table I is between the 5-10 micron range for one cut point.

The pre-separator 16 is shown in Figure 8 in exploded view and in Figure 9 in section. The pre-separator 16 includes a base particle collection plate 110, that has an outlet opening 112 leading into the inlet opening 14 of the impactor assembly 10. An impinger plate 114 is mounted above the collection plate 110 in use. The impinger plate includes an annular nozzle 116, with a plurality of openings 118

around the periphery of the impinger plate 114. The openings 118 have tapered inlet ends 118A, and are made so that there are approximately ten openings 118 around the periphery extending through the nozzle 116. The nozzle surrounds a cylindrical wall 120 that forms an impinger chamber 122 within the bounds of the wall 120. The impinger chamber 122 is a small reservoir, and includes a quantity of water that is directly below an inlet passage 124 in a cover 123 to which the standard inlet 125 is connected. When assembled, the interior chamber around the wall 120 is sealed, and air flowing in through the inlet opening 124 will be directed down onto the surface of the water in the impinger chamber 122, which will cause the heavier particles to separate into the impinger chamber while the flow and smaller particles will pass through the openings 118 of the nozzle 116 toward the surface 110A of the collection plate 110.

The impinger chamber 122 is designed so that most particles larger than approximately 20 microns and no smaller than 10 microns will strike the surface of the water when the inlet flow rate is 100 liters per minute. The remaining particles will then pass with the flow through the openings 118. The flow will accelerate in the openings so that all particles larger than 10 microns will collect on the surface 110A below the nozzle. The flow now ideally free of particles larger than 10 microns proceed through the opening 112 into the impactor inlet and to the first stage of the impactor 10.

The pre-separator can be quite small, for example, approximately 4 inches in diameter and 2.6 inches tall excluding the connecting fittings. The openings 118 have a diameter of .322 inches.

Approximately 20 ml of water will be in the impinger chamber 122, and the distance from the inlet to the surface of the water will be controlled so that air will flow around the top of the wall 120 and through the openings 118.

In Figures 13, 14 and 15, a modified stacked cup design impactor embodying the principles of the present invention is illustrated at 130. The impactor 130 includes several individual stages, one of which is shown in greater detail in Figure 15. The impactor 130 has an inlet shown schematically at 132 that leads to a first impactor housing 134. The impactor housings are made essentially identical, except that the direction of flow is reversed in the vertically adjacent impactor sections.

The first stage 134 receives the flow from the inlet 132 through a nozzle 133. The first stage housing 134 has a tear drop shaped chamber 134A. The large end comprises an impaction surface 134E, the flow then goes to the narrow end and through a cross or interstage passageway 134B and then through a nozzle passage 134C that has a nozzle plate 134D therein. The nozzle plate 134D is for the second stage impactor and has large openings. The flow will then pass into a second stage impactor housing 136, which forms a chamber 136A that is also tear drop shaped, as can be seen. The chamber 136A receives the flow and has an impactor surface 136E. As indicated by the arrows, the flow goes through a cross or interstage passageway 136B and then into a nozzle passageway 136C and through a third stage nozzle plate 136D that has smaller openings in it, than the second stage nozzle plate 134D as shown in Table I, for

example. A different selected size of opening can be selected for different cut points.

The third stage housing 138 includes a third stage chamber 138A through which the flow will pass. The housing 138 has an impaction surface 138E on which particle above the cut point will impinge. The flow enters an interstage passage 138B, and goes into a nozzle passage 138C and through a fourth stage nozzle plate 138D which again has smaller orifices or openings than the third stage nozzle plate 136D.

The flow then passes into a fourth stage housing 140, having a tear drop shaped chamber 140A. It is the fourth stage housing 140 that is shown in Figure 15. This again is typical of the housings that are shown. The particles above the cut point will impinge on fourth stage impactor surface 140E. The flow passes through an interstage passage 140B, and into a nozzle passageway 140C and through a fifth stage nozzle plate 140D. The opening size in nozzle plate 140D is selected to obtain the desired cut point.

The flow through the nozzle plate 140D enters a fifth stage housing 142, which has a tear drop shaped chamber 142A, and an impactor surface 142E that will serve as a collection plate for particles passing through the nozzle plate 140D that are above the cut off at this stage. The flow goes through an interstage passage 142B and into a nozzle passage 142C. The flow will pass through a further small opening sixth stage nozzle plate 142D. The flow then goes into a sixth stage housing 144, and the sixth stage housing 144 has an impaction surface 144E, in the chamber 144A. The flow then goes through an interstage passage 144B, and through a nozzle passage

144C and then through a seventh stage nozzle 144D into a chamber 146A of a seventh stage housing 146.

The seventh stage has a chamber 146A, with an impactor surface 146E. The flow will pass through an interstage passage 146B, through a nozzle passage 146C and through a micro orifice filter 146D having openings thereon to achieve the desired filtering. The flow will impinge on an impactor plate in housing 148 which has a chamber 148A that receives the flow from the filter 146D. The flow then will pass out through an outlet opening 148C. The micro orifice filter 148D has very fine openings in the nozzle plate as mentioned previously. A microporous filter can have in the range of 3100 openings, as shown in Table I.

The stacked design of Figures 13-15 uses the tear shaped chambers, as shown, to insure smooth flow, with little dead volume and thus little chance of having improper cut points.

A further modified form of the invention is shown in Figures 16, 17 and 18. An impactor 170 is a cylindrical form and the impactor stages are mounted one above the other, as is common.

The impactor assembly 170 has an inlet tube 172 that connects to a standard inlet as shown, and flow comes through the nozzle 173 into an inlet or first stage housing 174. Housing 174 has an impactor chamber 174A, with a impactor wall or plate portion 174B aligned with the inlet nozzle 173. The flow in this form of the invention is shown in Figure 16, and large particles will impinge on the surface of impaction plate 174B in the center portions of the wall. The impaction plate 174B is surrounded by an annular nozzle ring 174C that has a plurality of

orifices or openings 174D arranged around the periphery adjacent an exterior wall 174E. The flow then will pass through the chamber 174A and through the orifices or openings 174D into a second stage housing 176. The plate 174B and nozzle ring 174C are part of the top wall of the housing 176. The housing 176 is a ring 174E around plate 174B that has a shoulder 174F that receives an end of the housing wall 174E so the two housings nest together.

Housing 176 has a chamber 176A into which the flow through the openings 174D passes. Particles above the cut off size impact on the surface of an annular impaction on wall plate wall 176B. The particles above the cut point will be collected on this annular surface 176B, and the flow in the chamber 176A will then go inwardly toward the center of the chamber 176A and through a center nozzle section 176C in the center portions of the wall, which has a pattern of openings or orifices 176D therein. The orifices 176D are arranged in a square pattern as can be seen in Figure 17, and the pattern is made of a particular size, generally not more than two inches square, at each of the nozzle plates where the openings are in the center of the impactor plate.

The flow through the nozzle openings 176D will enter into a third impactor stage housing 178, that has a chamber 178A, with an impaction surface on an impaction plate 178B in the center of the chamber, to receive the flow coming through the nozzle openings 176C.

It should be noted that the walls forming the impaction surfaces are supported by the outer wall of the underlying housing, that is wall 174B is supported by 176E, and wall 176B is supported by wall

178B of housing 178. For convenience the impaction surfaces are described as part of the chambers above the walls. Also, the wall 176E has a lower flange that nests on a shoulder 178E of the outer wall 178E of housing 178.

The flow from nozzle 176C then goes outwardly toward the outer periphery of the housing 178, and enters an annular nozzle 178C that has a plurality of openings shown schematically at 178D. The openings in nozzle 178C are smaller than previous nozzles, so that the flow through the openings 178D will pass into a fourth impactor stage housing 180 of the impactor.

The fourth stage 180 has a chamber 180A, and immediately below the annular nozzle 178C, there is an annular impaction surface 180B to receive particles at the cut point for this stage. The flow then goes in toward the center, where there is a center nozzle 180C that has suitable openings, that are of size such that they do not show up in Figure 16. The flow through the nozzle 180C is through openings such as those shown in Figure 18. The openings are smaller but still in the square pattern. A shoulder 180F of a peripheral wall 180E supports a lower portion of wall 178E, which nests in place.

The flow through the nozzle 180C then passes into a fifth impactor stage housing 182 that has a chamber 182A, and a wall 182B defining an impaction surface is below nozzle 180E to collect particles at the cut point passing through nozzle 180C. The flow in chamber 182 then moves laterally outwardly to an annular nozzle 182C that again has smaller openings or orifices than the nozzle 180C.

CLAIMS:

1. An impactor for classifying particles according to size comprising a housing, a flow passageway through said housing, said flow passageway being divided into a plurality of individual passageway sections, a separate nozzle in each passageway section for carrying the flow between individual passageway sections, a particle collection chamber aligned with each nozzle and having an impaction surface to receive flow from the respective nozzle, each chamber having a output end joining other parts of said flow passage, said particle collection chamber having a large area portion immediately below its aligned nozzle, and having side walls tapering to a narrow portion at the output end of said collection chamber.

2. The impactor of claim 1, wherein said collection chamber has a large end wall formed along a radius at the large area portion and an output end wall having a substantially smaller radius at the output end, and the side walls comprising straight wall sections joining the large end and output end walls.

3. The impactor of claim 1, wherein each nozzle comprises a nozzle cup having a rim at an open inlet end, a support plate for the nozzle cups, said support plate having a tapered opening for receiving a rim of the respective nozzle cup, and a support rim formed in the tapered opening at a narrow end of the taper for engaging a rim on the respective nozzle cup to support the nozzle cup in a known position.

4. The impactor of claim 3, wherein each nozzle cup overlies a collection chamber and has a nozzle wall positioned at a selected distance from the impaction surface of the collection chamber.

5. The impactor of any one of claims 1 to 4, wherein said collector chamber comprises a removable cup, said removable cup having a peripheral flange, and a cup tray for supporting said removable cup, said cup tray being removably mounted in said housing.

6. The impactor of any one of claims 1 to 5, wherein there are a plurality of collection chambers, each of said collection chambers having a wide end for receiving flow from a nozzle, and a narrow end joining other portions of the flow path, said collection chambers being supported substantially on a plane, the narrow ends of the chambers overlapping, with the narrow end of each chamber being adjacent the wide end of an adjacent chamber so that the collection chambers nest together.

7. The impactor of claim 6, wherein said collection chambers are supported in a base portion of the housing, a cover portion of the housing hingedly connected to the base portion along one edge thereof, a portion of each flow path section between individual collection chambers being defined in said cover portion.

8. The impactor of claim 7, further comprising a seal plate between the base portion and the cover portion, said seal plate having sealing members surrounding the collection chambers on one side of the

seal plate, and second sealing members surrounding the portions of the flow path sections defined in the cover portion on the other side of the seal plate.

9. The impactor of claim 8 further comprising a latch for securing the base portion and the cover portion together, with the seal plate positioned between the base portion and cover portion, said seals on seal plate compressing as the latch is secured.

10. An impactor comprising a housing, said housing having an inlet and an outlet, and a flow path through the housing, said flow path being divided into at least two flow segments, a nozzle between the flow segments, a collection chamber for receiving flow from the nozzle and collecting particles that are carried in the flow, the improvement comprising a pre-separator at the inlet of the housing, said pre-separator including a chamber having an inlet tube and an outlet tube, and having tapered internal surfaces that taper toward one of the tubes for permitting draining of material on the interior of the pre-separator.

11. The impactor of claim 10, wherein said pre-separator includes a collection tank aligned with the inlet opening such that flow impinges on liquid in said collection tank, and before passing to the outlet.

12. An impactor for classifying particles according to size comprising a housing, said housing being made up of individual housing sections, said housing sections each including a nozzle, and an

impaction surface supported on substantially the same plane, and said housing sections being stacked, one on top another.

13. The impactor of claim 12, wherein said housings include chambers that taper from a wide end forming an impaction surface to a narrow end leading to a nozzle for providing a flow path.

14. The impactor of claim 12, wherein said housing sections are generally circular in cross section, and each of said housing sections have a portion that defines a nozzle, and a second portion that defines an impaction surface.

15. The impactor of claim 14, wherein said housing sections alternately have the portions forming a nozzle in center portions of the chamber, and the impaction surfaces annularly round the center portion, and in alternate housing sections having nozzles in the annular portion and an impaction surface in the center portion.

16. An impactor substantially as hereinbefore described with reference to the accompanying drawings.